K080430

NOV 21 2008

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

DATE: February 8th, 2008

APPLICANT: Storz am Mark GmbH
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1. Device Name

Trade Name: STOMA Bone Block Screw, Steel
Common Name: Bone Screw

2. Classification

The products are classified according following Device Names and Product Codes:

Device:	Screw, Fixation, Intraosseous
Medical Specialty:	Dental
Product Code:	DZL
Regulation Number:	872.4880
Device Class:	2
Description acc. 21 CFR 872.4880: Subpart E -- Surgical Devices Sec. 872.4880 Intraosseous fixation screw or wire. (a) *Identification.* An intraosseous fixation screw or wire is a metal device intended to be inserted into fractured jaw bone segments to prevent their movement. (b) *Classification.* Class II.	

3. Description of the Device

3.1. Indication for Use

STOMA bone block screws are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process in the oral cavity and maxillomandibular surgical field.

STOMA bone block screws are not intended to remain in the body permanently. After they have fulfilled their supportive function such as is the case after healing of a transplant, or healing of a fracture, for example, they need to be removed completely.

3.2. Properties

The screw head has either

- an inner square, or
- a cross slot.

The screw thread is self-tapping and has two different thread leads.

Dimensions:

- Length: 4 mm, 6 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm
- Diameter: ø1.0 mm, ø1.2 mm, ø1.6 mm.

The screws can be delivered in a cassette along with suitable accessories such as a screwdriver and pilot drill as basic equipment or re-ordered separately in different packaging units.

4. Substantial Equivalence Comparison

STOMA Bone Block Screws are substantially equivalent to STOMA Bone Screws (K51871).

5. Biocompatibility

All requirements of biocompatibility are met through the composition of the used raw material.

6. Sterilization by User

STOMA Bone Block Screws are delivered in non-sterile conditions. The user may sterilize these devices by using a validated steam-sterilization process according ISO 11134 that uses a sterilization cycle of 137°C / 280°F, 3 bar, for min. 15 minutes.

7. Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that STOMA Bone Screws are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2009

Storz am Mark GmbH
C/O Mr. Franz Menean
Managing Director
MEDAGENT GmbH & Company KG
Griesweg 47
Muehlheim, Baden-Wuerttemberg
GERMANY 78570

Re: K080430
Trade/Device Name: STOMA Bone Block Screw, Steel
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: November 12, 2008
Received: November 14, 2008

Dear Mr. Menean:

This letter corrects our substantially equivalent letter of November 21, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K080430**

Device Name: **STOMA Bone Block Screw, Steel**

Indications for Use:

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Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080430